DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

APR 22 2004

Mr. W. Paul Stewart
CEO
Custom Nutrition Laboratories
8700 Diplomacy Row
Dallas, Texas 75247

Dear Mr. Stewart:

This is in response to your letter of February 26, 2004 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Custom Nutrition Laboratories is making the following claims, among others, for the product **Iso-Plex™ Joint Care**:

> "Reduce pain & inflammation"
> "...game and life-style being altered by joint pains...beneficial step in correcting my joint pain."

These claims are disease claims because they suggest that the product is intended to treat, prevent, or mitigate diseases, namely joint disorders such as arthritis. In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1016-17), FDA stated that "joint pain" is characteristic of arthritis and that it is the most sensitive physical sign of rheumatoid arthritis. For that reason, the agency concluded that claims about relieving joint pain are implied disease claims because they represent that the product will have an affect on a characteristic sign or symptom of a disease (see 21 CFR 101.93(g)(2)(ii)). Moreover, elsewhere in the preamble to the final rule (see 65 FR 1000 at 1030) FDA discussed the circumstances under which claims about pain would imply disease treatment. We stated that since pain is not a normal state, nor are there "normal pain levels," a claim about pain treatment or prevention is ordinarily a disease claim. We addressed the issue of joint pain claims in particular, noting that such claims are disease claims because joint pain is a characteristic symptom of arthritis. We added, however, that a acceptable structure/function claim could be made for pain associated with non-disease states, such as muscle pain following exercise.

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The claims contained in your notifications do not refer to pain associated with a non-disease state. Although all joint conditions that limit mobility or range of motion may not constitute diseases, they would not be expected to result in joint pain unless a person already suffered from an underlying disease that predisposed him or her to such pain; moreover, your claim "rebuild and repair joints" implicitly establishes that there are pre-existing conditions associated with the pain that your product is intended to alleviate.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to treat, prevent, or mitigate diseases. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20852.

Please contact us if we may be of further assistance.

Sincerely yours,

Susan J. Walker, M.D.
Director
Division of Dietary Supplement Programs
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200
FDA, Dallas District Office, Office of Compliance, HFR-SW140

CNL Custom Nutrition Laboratories

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February 26, 2004

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, DC 20204

To Whom It May Concern:

With this correspondence, we are notifying your office of our compliance with Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act concerning our newly introduced supplement into the marketplace.

Custom Nutrition Laboratories (address shown above) is the manufacturer of the following product:

Iso-Plex™ Joint Care

We have attached the product literature and pouch used for distribution of this product.

I hereby certify that the information contained in this notice is complete and accurate, and that we have substantiation that the statements on the product labeling are truthful and not misleading.

Sincerely,

W. Paul Stewart, CEO

WPS:dkw

Enclosures

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